



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2020-N-0257]**

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Rapid Response Surveys**

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0500. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Drug Administration Rapid Response Surveys

OMB Control Number 0910-0500--Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) requires that important safety information relating to all human prescription drug products be made available to FDA so that the Agency can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA.

These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for Agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. FDA's regulations governing Agency oversight of Foods, Cosmetics, Dietary Supplements, and Animal Food and Feed (21 CFR parts 70 through 199) also implement these statutory provisions. Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using Forms FDA 3500 and 3500A (OMB control number 0910-0291), electronic Safety Reporting Portal (OMB control number 0910-0645), and the vaccine adverse event reporting system.

FDA is seeking extension of OMB approval to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community-based healthcare professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other healthcare professionals, patients, consumers, and risk managers working in facilities containing products related to or regulated by FDA. FDA will use the information gathered from these surveys to quickly obtain vital information about medical product risks and interventions to reduce risks so the Agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA projects six emergency risk related surveys per year with a sample of between 50 and 10,000 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA may be able

to obtain by working with healthcare professional organizations. The annual number of surveys was determined by the maximum past number of surveys per year FDA has conducted under this collection.

Respondents to this collection of information will be identified when additional surveillance data will address a potential public health hazard. For example, respondents could include facilities or professionals that have the most experience in the use of certain FDA-regulated products, foods, cosmetics, dietary supplements, animal food and feed, drugs, tobacco products, etc. Once FDA identifies the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified either through FDA's lists or through the appropriate professional organizations.

In the *Federal Register* of February 5, 2020 (85 FR 6559), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA Rapid Response Survey	10,000	6	60,000	0.5 (30 minutes)	30,000

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 12, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

